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PATENT

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Susan M. Barry
Printed name of person mailing correspondence

Susan M. Barry
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Bruno Guy et al.	Art Unit:	1645
Serial No.:	09/423,042	Examiner:	V. Portner
Filed:	October 29, 1999	Customer No.:	21559
Title:	Anti-Helicobacter Vaccine Composition for Use by the Subdiaphragmatic Systemic Route, and Combined Mucosal/Parenteral Immunization Method		

Assistant Commissioner for Patents
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. § 1.132

I declare:

1. I am an inventor of the subject matter that is described and claimed in the above-captioned patent application.

2. I currently hold the position of Director of Clinical Research at Acambis, Inc., which is an owner of this application and where I have been working for over ten years.

3. Experiments were carried out at Acambis to determine the efficacy of a mucosal prime, parenteral boost regimen in the prophylaxis of Helicobacter infection. Groups of ten, six to eight week old female Swiss-Webster (Taconic) mice were immunized by the mucosal prime, parenteral boost regimens summarized in the enclosed table. As is shown in the enclosed graph, the results of these experiments show that these regimens have prophylactic efficacy, with several antigens, as indicated.

4. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true; further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Date: _____ _____

Cynthia K. Lee, Ph.D.

Animal Experiment Form

Experiment title: Evaluation of CLASS I antigens using a rectal mucosal prime/parenteral boost regimen

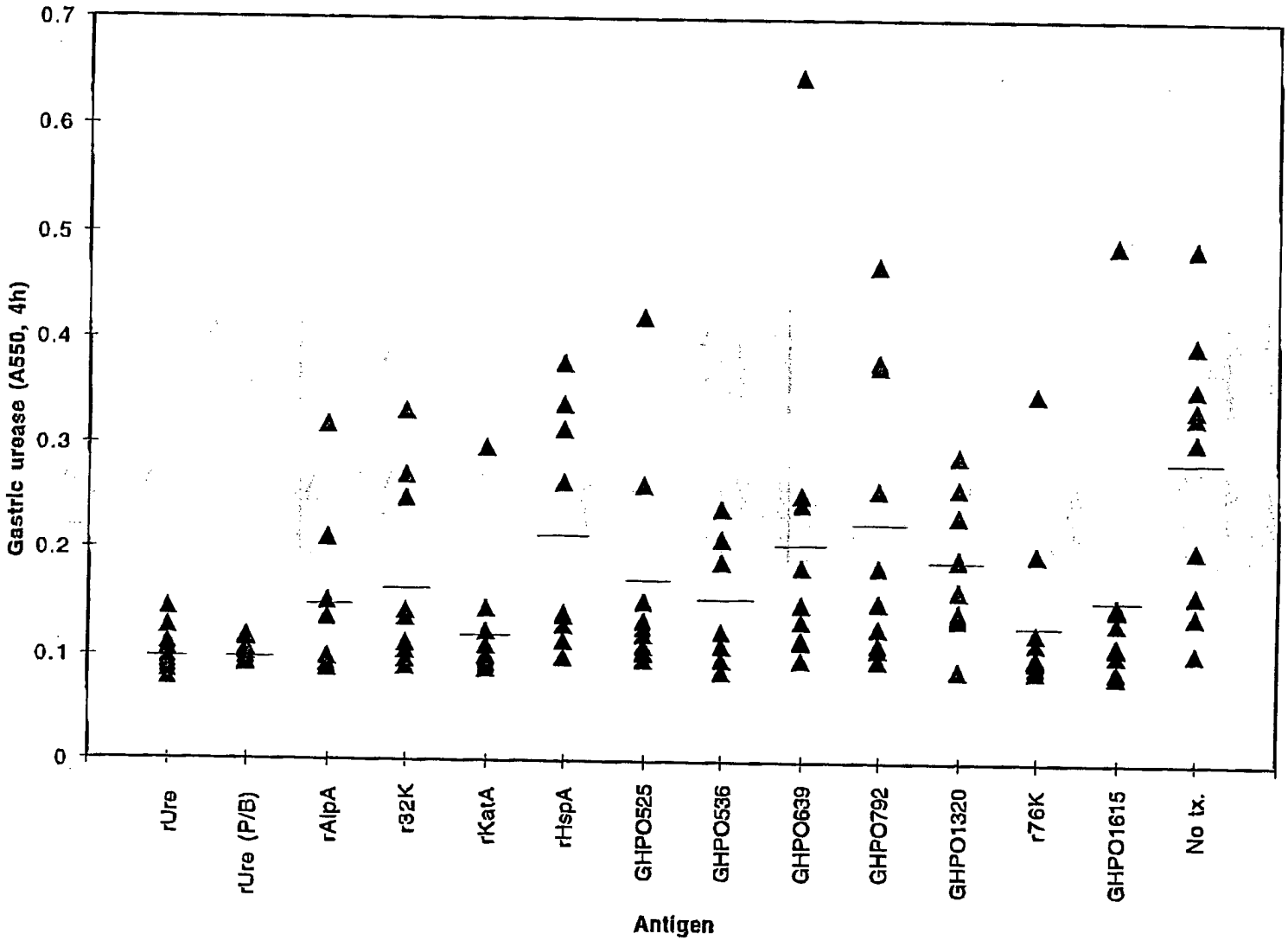
Objectives: Compare efficacy of CLASS I antigens using a rectal mucosal prime (LT) / parenteral boost (Alum) immunization regimen
Animal model: 6-8 wk. old, female, Swiss-Webster mice (Taconic).

Schedule and Design:

Group	# Mice	Dose antigen	Dose adjuvant (P-prime;B-boost)	Route	Schedule	Post-imm. samples	Challenge	Sac
1	10	rUre (25 µg)	LT (500 ng)	Rectal	d. 0, 21, 42	d. 53 (blood)	d. 56 (1 x 10^7 X47-2AL)	d. 84 (Gast. urease, culture, histology)
2	10	rUre (25 µg) P (10 µg) B	P: LT (500 ng) B: Alum (200 µg)	Rectal SC (back)	d. 0 d. 21, 42	"	"	"
3	10	rAlpA (25 µg) P (10 µg) B	"	"	"	"	"	"
4	10	r32K (25 µg) P (10 µg) B	"	"	"	"	"	"
5	10	rKatA (25 µg) P (10 µg) B	"	"	"	"	"	"
6	10	rHspA (25 µg) P (10 µg) B	"	"	"	"	"	"
7	10	GHPO525 (25 µg) P (10 µg) B	"	"	"	"	"	"
8	10	GHPO536 (25 µg) P (10 µg) B	"	"	"	"	"	"
9	10	GHPO639 (25 µg) P (10 µg) B	"	"	"	"	"	"

10	10	GHPO792 (25 µg) P (10 µg) B	"	"	"	"	"	"	
11	10	GHPO1320 (25 µg) P (10 µg) B	"	"	"	"	"	"	
12	10	r76K (25 µg) P (10 µg) B	"	"	"	"	"	"	
13	10	GHPO1615 (25 µg) P (10 µg) B	"	"	"	"	"	"	
14	10	None	None	-	-	"	"	"	

Exp. 203: Comparative efficacy of Class I antigens using a rectal mucosal prime/parenteral boost regimen



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